

stringent conditions with the target polynucleotide sequence to form a stable hybridization complex;
and

detecting the formation of a hybridization complex, wherein an amplification of said target polynucleotide sequence indicates that said cell is a neoplastic cell.

These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with the Examiner's position. In accordance with the requirements of 37 C.F.R. § 1.121, a marked up version showing the changes to the claims, is attached herewith as Appendix A. For the Examiner's convenience, a complete claim set of the currently pending claims is also submitted herewith as Appendix B.

REMARKS

Status of the Claims.

Claims 26-28,k are pending with entry of this amendment, claims no claims being cancelled and no claims being added herein. Claim 26 is amended herein. This amendment introduces no new matter.

Change in correspondence address.

Applicants note that a Revocation and Substitute Power of Attorney incorporating a change in correspondence address was filed on April 30, 2001. For the convenience of the Examiner, a copy of this document is enclosed. In accordance with the instructions provided therein, Please direct all future correspondence regarding the subject application to CUSTOMER NUMBER 22798, that is:



22798

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35 U.S.C. §102.

Claims 26-28 and 37 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Tanner *et al.* (1995) *Clin.. Cancer Res.*, 1: 1455-1461 or Tanner *et al.* (1996) 56: 3441-3445. In particular, the Examiner noted that the claims were drawn to a method of screening cells that

involved contacting a sample "to a probe that selectively hybridizes under stringent conditions to a target polynucleotide sequence **comprising SEQ ID NO: 9** . . . ". The Examiner further alleged that a target polynucleotide sequence comprising the genomic sequence of SEQ ID NO:9 is contained within the region of chromosome 20 spanned by the RMC20C001 probe. Applicants respectfully traverse.

Claim 26, is amended herein to recite:

[C]ontacting a nucleic acid sample from a human patient with a probe which hybridizes selectively to a target polynucleotide sequence **consisting essentially of** a sequence selected from the group consisting of SEQ. ID. No. 9, and SEQ. ID. No. 10 . . .

thereby obviating the rejection. Applicants further note that this "consisting essentially of" language is similar in form to that indicated as allowable in related application USSN 08/132,808 (now U.S. Patent 5,472,842).

In view of this amendment, Applicants respectfully request that the rejection under 35 U.S.C. §102(a) be withdrawn.

35 U.S.C. §101.

Claims 36 and 36 were provisionally rejected under 35 U.S.C. §101, as allegedly claiming the same invention of claims 35 and 36 of copending application 08/731,499. Applicants note that presently pending claims 35 and 36 are directed to methods of use while the claims of 08/731,499 are directed to compositions of matter. Accordingly the claims are not directed to the same invention and the rejection under 35 U.S.C. §101 is improper and should be withdrawn.

Obviousness-type double patenting.

Claims 26-28, 36 and 37 were rejected under the judicially created doctrine of obviousness-type double patenting allegedly being unpatentable over claims 24-26, 35-36, and 38 of copending Application No: 08/731,499. Claims 26-28, 36 and 37 were rejected under the judicially created doctrine of obviousness-type double patenting allegedly being unpatentable over claims 26-28, 37-38, 56-57, and 61-63 of copending Application No: 08/785,532. Upon an indication of otherwise allowable subject matter, Applicants will provide a Terminal Disclaimer thereby obviating this rejection.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 337-7871.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Tom Hunter", with a stylized, cursive script.

Tom Hunter
Reg. No: 38,498

APPENDIX A

**"MARKED UP" CLAIMS ILLUSTRATING THE AMENDMENTS MADE TO THE
CLAIMS OF 08/892,695 WITH ENTRY OF THIS AMENDMENT**

26. (Twice amended) A method of screening for neoplastic cells in a sample, the method comprising:

contacting a nucleic acid sample from a human patient with a probe which hybridizes selectively to a target polynucleotide sequence [~~comprising~~ consisting essentially of a sequence selected from the group consisting of SEQ. ID. No. 9, and SEQ. ID. No. 10, wherein the probe is contacted with the sample under conditions in which the probe specifically hybridizes under stringent conditions with the target polynucleotide sequence to form a stable hybridization complex; and

detecting the formation of a hybridization complex, wherein an amplification of said target polynucleotide sequence indicates that said cell is a neoplastic cell.

27. The method of claim 26, wherein the nucleic acid sample is from a patient with breast cancer.

28. (Once amended) The method of claim 26, wherein the nucleic acid sample is a metaphase spread or an interphase nucleus.

36. The method of claim 26, wherein the probe comprises a polynucleotide sequence as set forth in SEQ. ID. No. 9.

37. The method of claim 26, wherein the probe comprises a polynucleotide sequence as set forth in SEQ. ID. No. 10.